IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. SANDOZ INC. AND SANDOZ INTERNATIONAL GMBH, Defendants.	C.A. No. 19-2080-LPS

SANDOZ INC.'S ANSWER, DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant Sandoz Inc. ("Sandoz") hereby files its Answer, Defenses and Counterclaims in response to the Complaint of Otsuka Pharmaceuticals Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs").

All responses from Sandoz are made solely on behalf of Sandoz Inc., and no response is made to any allegation that is properly directed to any Defendant other than Sandoz Inc., because none is required. *See* Fed. R. Civ. P. 8(b)(1)(B). In particular, Sandoz Inc. objects to Plaintiffs' definition of "Sandoz" as including, collectively, Sandoz Inc. and Sandoz International GmbH. This Answer is on behalf of Sandoz Inc. only and all references to "Sandoz" in this Answer refer only to Sandoz Inc. Pursuant to Fed. R. Civ. P. 8(b)(3), Sandoz denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent"), 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent"), and 10,307,419 ("the '419 patent") (collectively, "patents in suit"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Sandoz's filing of an Abbreviated New Drug Application

("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use or sale of generic pharmaceutical products before the expiration of the patents in suit.

RESPONSE: Paragraph 1 contains conclusions of law to which no response is required. To the extent a response is required, Sandoz admits that the Complaint purports to state an action for infringement of U.S. Patent Nos. 7,888,362 ("'362 patent"), 8,349,840 ("'840 patent"), 8,618,109 ('109 patent"), 9,839,637 ("'637 patent"), and 10,307,419 ("'419 patent") arising under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* Sandoz further admits that Abbreviated New Drug Application ("ANDA") No. 213570 seeks approval from the U.S. Food and Drug Administration ("FDA") to engage in the commercial manufacture, use or sale of the products that are the subject of ANDA No. 213570 ("Sandoz's ANDA Products"). Sandoz denies the remaining allegations in Paragraph 1 of the Complaint.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

RESPONSE: Paragraph 2 contains a legal conclusion to which no response is required. To the extent that a response is required, Sandoz lacks sufficient knowledge and information to form a belief as to the allegations of Paragraph 2, and therefore denies the same.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the '362, '840, '109, '637 and '419 patents.

RESPONSE: Paragraph 3 contains a legal conclusion to which no response is required. To the extent that a response is required, Sandoz lacks sufficient knowledge and information to form a belief as to the allegations of Paragraph 3, and therefore denies the same.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

RESPONSE: Sandoz is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4, and therefore denies the same.

5. Upon information and belief, Sandoz GmbH is a corporation organized under the laws of Germany and its principal place of business is located at Industriestrasse 25, 83607 Holzkirchen, Germany.

RESPONSE: Paragraph 5 contains factual allegations directed to Sandoz International GmbH to which no response is required. To the extent a response is required, Sandoz denies the allegations in Paragraph 5 of the Complaint.

6. Upon information and belief, Sandoz Inc. is a corporation organized under the laws of Colorado and its principal place of business is located at 100 College Rd. West, Princeton, NJ 08540. Upon information and belief, Sandoz Inc. is a majority owned subsidiary of Sandoz GmbH.

RESPONSE: Sandoz admits it is a corporation organized under the laws of Colorado with a principal place of business at 100 College Rd. West, Princeton, NJ 08540. To the extent paragraph 6 contains factual allegations directed to Sandoz International GmbH, no response is required. Except as expressly admitted, Sandoz denies the allegations in Paragraph 6 of the Complaint.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

RESPONSE: Paragraph 7 contains a legal conclusion to which no response is required. To the extent that a response is required, for purposes of this actions only, Sandoz does not contest that this Court has jurisdiction over the subject matter of the Complaint as to Sandoz, pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, venue and jurisdiction are proper for this proceeding.

RESPONSE: Paragraph 8 contains a legal conclusion to which no response is required. To the extent that a response is required, for purposes of this case only, Sandoz does not contest venue and jurisdiction as to Sandoz, and expressly reserves the right to contest jurisdiction in any other case as to any party, including Plaintiffs.

9. Plaintiffs believe this case belongs in Delaware but are concurrently filing a case in Colorado out of an abundance of caution.

RESPONSE: Sandoz lacks sufficient knowledge and information to form a belief as to the allegations of Paragraph 9, and therefore denies the same.

10. This Court has personal jurisdiction over Sandoz GmbH. Upon information and belief, Sandoz GmbH is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sandoz GmbH directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Sandoz GmbH purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Sandoz's generic products.

RESPONSE: Paragraph 10 contains factual allegations directed to Sandoz International GmbH to which no response is required. To the extent a response is required, Sandoz denies the allegations in Paragraph 10 of the Complaint.

11. Upon information and belief, "Sandoz International GmbH develops, produces, and distributes generic pharmaceuticals." https://www.bloomberg.com/profile/company/9018001Z:GR (Sandoz GmbH Bloomberg Profile, accessed Oct. 30, 2019). Upon information and belief, Sandoz GmbH "caters their products worldwide." *Id.* Upon information and belief, Sandoz GmbH's pharmaceutical products are available in more than 90 countries, including in the United States. *See* https://twitter.com/Sandoz_Global/status/1148894947027968000?s=20 (accessed Oct. 31, 2019). Upon information and belief, Sandoz GmbH admits that it is "honored to be named [McKesson's] 2019 Specialty Generic Partner of the Year! It's a privilege to be recognized for our efforts to expand patient access to high-quality medicines in the US." https://twitter.com/Sandoz_Global/status/1144606420282855425?s=20 (accessed Oct. 31, 2019). Upon information and belief, Sandoz GmbH admits it ranks third in the U.S. per IQVIA data. https://www.sandoz.com/sites/www.sandoz.com/files/sandoz-pocket-book.pdf at 9 (accessed Oct. 31, 2019); *see also* https://accessiblemeds.org/sites/default/files/2019-02/Doug-LongAccess2019.pdf at 30 (accessed Nov. 1, 2019) (IQVIA report indicating that Sandoz ranks third in unbranded generic non-discounted spend in the United States).

RESPONSE: Paragraph 11 contains factual allegations directed to Sandoz International GmbH to which no response is required. To the extent a response is required, Sandoz denies the allegations in Paragraph 11 of the Complaint.

12. This Court has personal jurisdiction over Sandoz Inc. Upon information and belief, Sandoz Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Sandoz Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Sandoz Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Sandoz's generic products.

RESPONSE: Paragraph 12 contains a legal conclusion to which no response is required. To the extent a response is required, for purposes of this case only, Sandoz does not contest personal jurisdiction as to Sandoz, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Sandoz admits that it seeks regulatory approval of, markets, and sells generic drug products in the United States. Sandoz denies the remaining allegations in Paragraph 12 of the Complaint.

13. Upon information and belief, "Sandoz Inc. manufactures, markets and/or distributes more than 295 drugs in the United States." https://www.drugs.com/manufacturer/sandoz-inc-125.html (accessed Oct. 30, 2019); *see also* https://www.us.sandoz.com/patientscustomers/products (accessed Oct. 31, 2019).

RESPONSE: Sandoz admits that it seeks regulatory approval of, markets, and sells generic drug products in the United States. Sandoz denies the remaining allegations in Paragraph 13 of the Complaint.

14. Upon information and belief, Sandoz Inc. is the United States agent for Sandoz GmbH.

RESPONSE: Sandoz Inc. denies the allegations of paragraph 14.

15. Upon information and belief, Sandoz GmbH and Sandoz Inc. hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

RESPONSE: Sandoz Inc. denies the allegations of paragraph 15.

16. Upon information and belief, Sandoz GmbH and Sandoz Inc. admit Sandoz GmbH is the "Global (Germany)" office and Sandoz Inc. is the "United States" office for Sandoz. https://www.sandoz.com/about-us/contact-us (accessed Oct. 30, 2019).

RESPONSE: Sandoz Inc. denies the allegations of paragraph 16.

17. Sandoz's ANDA filing regarding the patents in suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Sandoz's intent to market and sell Sandoz's generic products in this judicial district.

RESPONSE: Paragraph 17 contains a legal conclusion to which no response is required. To the extent that a response is required, for purposes of this case only, Sandoz does not contest venue and jurisdiction as to Sandoz, and expressly reserves the right to contest jurisdiction in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations in Paragraph 17 of the Complaint.

18. Sandoz has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Sandoz intends to direct sales of its generic drugs in this judicial district, among other places, once Sandoz receives the requested FDA approval to market its generic products. Upon information and belief, Sandoz will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

RESPONSE: Paragraph 18 contains a legal conclusion to which no response is required. To the extent that a response is required, for purposes of this case only, Sandoz does not contest venue and jurisdiction as to Sandoz, and expressly reserves the right to contest jurisdiction in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations in Paragraph 18 of the Complaint.

19. Upon information and belief, Sandoz has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213570.

RESPONSE: Sandoz admits that Sandoz Inc. prepared and submitted ANDA No. 213570 to the FDA. To the extent that paragraph 19 contains factual allegations directed to Sandoz

International GmbH, no response is required. Sandoz denies the remaining allegations of Paragraph 19.

FACTUAL BACKGROUND

The NDA

20. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3 and 4 mg dosage forms ("REXULTI® Tablets").

RESPONSE: Sandoz admits that the electronic version of the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), identifies Otsuka as the purported holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg. Sandoz denies the remaining allegations in Paragraph 20 of the Complaint.

21. The FDA approved NDA No. 205422 on July 10, 2015.

RESPONSE: Sandoz admits that the Orange Book identifies the approval date for NDA No. 205422 as July 10, 2015. Sandoz denies the remaining allegations in Paragraph 21 of the Complaint.

22. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

RESPONSE: Sandoz admits that the "Indication and Usage" section of the REXULTI® label states that REXULTI® is indicated for "[u]se as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD)" and the "[t]reatment of schizophrenia." Sandoz further admits that the "Medication Guide" section of the label states brexpiprazole is the active ingredient in REXULTI® Tablets. Sandoz denies the remaining allegations in Paragraph 22 of the Complaint.

The Patents In Suit

23. The United States Patent and Trademark Office ("the PTO") issued the '362 patent on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '362 patent is attached as Exhibit A.

RESPONSE: Sandoz admits that the '362 patent is entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" and bears an issue date of February 15, 2011. Sandoz further admits that what purports to be a copy of the '362 patent was attached to the Complaint as Exhibit A. Sandoz denies the remaining allegations of Paragraph 23.

24. Otsuka owns the '362 patent through assignment as recorded by the PTO at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

RESPONSE: Paragraph 24 contains a legal conclusion to which no response is required. To the extent that a response is required, Sandoz admits that what purports to be an assignment of the '362 patent to Otsuka was recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746; and Reel 048501, Frame 0122. Sandoz denies the remaining allegations of Paragraph 24.

25. The '362 patent currently expires on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed the 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

RESPONSE: Paragraph 25 contains a legal conclusion to which no response is required. To the extent that a response is required, Sandoz admits that the Orange Book identifies the expiration date for the '362 patent as April 12, 2026. Sandoz further admits that what purports to be a copy of the terminal disclaimer was attached to the Complaint as Exhibit B. Sandoz further admits that the 317 days of patent term adjustment granted to the '362 patent has been purportedly disclaimed. Sandoz denies the remaining allegations of Paragraph 25.

26. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application under 35 U.S.C. § 156 and Response to Notice of Final Determination, which is attached as Exhibit C. In Exhibit C, Otsuka requests an extension under 35 U.S.C. § 156(c) of

986 days. Accordingly, the '362 patent will expire on December 23, 2028, if granted the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

RESPONSE: Paragraph 26 contains a legal conclusion to which no response is required. To the extent that a response is required, Sandoz admits that what purports to be a copy of Otsuka's submission for Patent Term Extension for the '362 patent was attached to the Complaint as Exhibit C. Sandoz further admits that the application requests an extension of 986 days and the '362 will expire on December 23, 2028 if granted. Sandoz denies the remaining allegations of Paragraph 26.

27. The '362 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

RESPONSE: Sandoz admits the allegations of Paragraph 27.

28. The PTO issued the '840 patent on January 8, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '840 patent is attached as Exhibit D.

RESPONSE: Sandoz admits that the '840 patent is entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" and bears an issue date of January 8, 2013. Sandoz further admits that what purports to be a copy of the '840 patent was attached to the Complaint as Exhibit D. Sandoz denies the remaining allegations of Paragraph 28.

29. Otsuka owns the '840 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

RESPONSE: Paragraph 29 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz admits that what purports to be an assignment of the '840 patent to Otsuka was recorded by the PTO at Reel 048501, Frame 0166 and Reel 048501, Frame 0122. Sandoz denies the remaining allegations in Paragraph 29 of the Complaint.

30. The '840 patent is subject to a terminal disclaimer and expires on April 12, 2026.

RESPONSE: Paragraph 30 contains a legal conclusion to which no response is required. To the extent that a response is required, Sandoz admits that a terminal disclaimer was filed for the '840 patent. Sandoz further admits that the Orange Book identifies the expiration date for the '840 patent as April 12, 2026. Sandoz denies the remaining allegations in Paragraph 30 of the Complaint.

31. The '840 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

RESPONSE: Sandoz admits the allegations of Paragraph 31.

32. The PTO issued the '109 patent on December 31, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '109 patent is attached as Exhibit E.

RESPONSE: Sandoz admits that the '109 patent is entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" and bears an issue date of December 31, 2013. Sandoz further admits that what purports to be a copy of the '109 patent was attached to the Complaint as Exhibit E. Sandoz denies the remaining allegations of Paragraph 32.

33. Otsuka owns the '109 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

RESPONSE: Paragraph 33 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz admits that what purports to be an assignment of the '109 patent to Otsuka was recorded by the PTO at Reel 048501, Frame 0166 and Reel 048501, Frame 0122. Sandoz denies the remaining allegations of Paragraph 33.

34. The '109 patent is subject to a terminal disclaimer and expires on April 12, 2026.

RESPONSE: Paragraph 34 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz admits that a terminal disclaimer was filed for the '109 patent. Sandoz further admits that the Orange Book identifies the expiration date for the '109 patent as April 12, 2026. Sandoz denies the remaining allegations of Paragraph 34.

35. The '109 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

RESPONSE: Sandoz admits the allegations of Paragraph 35.

36. The PTO issued the '637 patent on December 12, 2017, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '637 patent is attached as Exhibit F.

RESPONSE: Sandoz admits that the '637 patent is entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" and bears an issue date of December 12, 2017. Sandoz further admits that what purports to be a copy of the '637 patent was attached to the Complaint as Exhibit F. Sandoz denies the remaining allegations of Paragraph 36.

37. Otsuka owns the '637 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

RESPONSE: Paragraph 37 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz admits that what purports to be an assignment of the '637 patent to Otsuka was recorded by the PTO at Reel 048501, Frame 0166 and Reel 048501, Frame 0122. Sandoz denies the remaining allegations in Paragraph 37 of the Complaint.

38. The '637 patent is subject to a terminal disclaimer and expires on April 12, 2026.

RESPONSE: Paragraph 38 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz admits that a terminal disclaimer was filed for the '637 patent. Sandoz further admits that the Orange Book identifies the expiration date for the '637 patent as April 12, 2026. Sandoz denies the remaining allegations in Paragraph 38 of the Complaint.

39. The '637 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

RESPONSE: Sandoz admits the allegations of Paragraph 39.

40. The PTO issued the '419 patent on June 4, 2019, entitled "Tablet Comprising 7-[4(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof." A true and correct copy of the '419 patent is attached as Exhibit G.

RESPONSE: Sandoz admits that the '419 patent is entitled "Tablet Comprising 7-[4(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof" and bears an issue date of June 4, 2019. Sandoz further admits that what purports to be a copy of the '419 patent was attached to the Complaint as Exhibit G. Sandoz denies the remaining allegations of Paragraph 40.

41. Otsuka owns the '419 patent through assignment as recorded by the PTO at Reel 033930, Frame 0447.

RESPONSE: Paragraph 41 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz lacks sufficient knowledge and information to form a belief as to the allegations in Paragraph 41, and therefore denies the same.

42. The '419 patent expires on October 12, 2032.

RESPONSE: Paragraph 42 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz admits that the Orange Book identifies the expiration date for the '419 patent as October 12, 2032. Sandoz denies the remaining allegations in Paragraph 42 of the Complaint.

43. The '419 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

RESPONSE: Sandoz admits the allegations of Paragraph 43.

The ANDA

44. Upon information and belief, Sandoz filed ANDA No. 213570 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg ("Sandoz's generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

RESPONSE: Sandoz admits that it is seeking FDA approval to engage in the commercial manufacture, use or sale of Sandoz's ANDA Products. Sandoz denies the remaining allegations of Paragraph 44.

45. Upon information and belief, ANDA No. 213570 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the patents in suit are invalid, unenforceable and/or would not be infringed by Sandoz's generic products.

RESPONSE: Sandoz admits the allegations of Paragraph 45.

46. Otsuka received a letter sent by Sandoz, dated September 18, 2019, purporting to be a "Notice of Certification" for ANDA No. 213570 ("Sandoz's Notice Letter") pursuant to § 505(j)(2)(B)(ii)-(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Sandoz's Notice Letter notified Otsuka that Sandoz had filed ANDA No. 213570, seeking approval to engage in the commercial manufacture, use or sale of Sandoz's generic products before the expiration of the patents in suit.

RESPONSE: Sandoz admits that it sent a letter dated September 18, 2019 ("Notice Letter") to Otsuka. Sandoz admits that the Notice Letter provided Otsuka with written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that, *inter alia*, Sandoz submitted ANDA No. 213570 to the FDA. Sandoz denies the remaining allegations of Paragraph 46.

47. Plaintiffs commenced this action within 45 days of receiving Sandoz's Notice Letter.

RESPONSE: Sandoz is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47, and therefore denies the same.

COUNT I
(INFRINGEMENT OF THE '362 PATENT)

48. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

RESPONSE: Paragraph 48 contains no allegations of fact to which a response is required. To the extent a response is required, Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

49. Upon information and belief, Sandoz filed ANDA No. 213570 seeking approval to manufacture, use, import, offer to sell and/or sell Sandoz's generic products in the United States before the expiration of the '362 patent.

RESPONSE: Sandoz admits that it is seeking FDA approval to commercially manufacture, use, or sell Sandoz's ANDA Products in the United States. Sandoz denies the remaining allegations in Paragraph 49.

50. Upon information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '362 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Sandoz admits the allegations of Paragraph 50.

51. Upon information and belief, in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

RESPONSE: Sandoz admits that in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's ANDA Products are bioequivalent to the corresponding strengths of REXULTI® Tablets. Sandoz denies the remaining allegations of Paragraph 51.

52. Sandoz has actual knowledge of Otsuka's '362 patent, as evidenced by Sandoz's Notice Letter.

RESPONSE: Sandoz admits that it was aware of the '362 patent at least as early as September 18, 2019. Sandoz denies the remaining allegations of Paragraph 52.

53. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed one or more claims of the '362 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213570, seeking approval to commercially manufacture, use, import, offer to sell or sell Sandoz's generic products before the expiration date of the '362 patent.

RESPONSE: Paragraph 53 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 53.

54. Upon information and belief, if ANDA No. 213570 is approved, Sandoz intends to and will offer to sell, sell and/or import in the United States Sandoz's generic products.

RESPONSE: Paragraph 54 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 54.

55. Upon information and belief, if ANDA No. 213570 is approved, Sandoz will infringe one or more claims of the '362 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Sandoz's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213570 shall be no earlier than the expiration of the '362 patent and any additional periods of exclusivity.

RESPONSE: Paragraph 55 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 55.

56. Upon information and belief, Sandoz's actions relating to Sandoz's ANDA No. 213570 complained of herein were done by and for the benefit of Sandoz.

RESPONSE: Sandoz admits that Sandoz Inc. prepared and submitted ANDA No. 213570 to the FDA. Sandoz denies the remaining allegations of Paragraph 56.

57. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless this Court enjoins those activities.

RESPONSE: Paragraph 57 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 57.

58. Plaintiffs do not have an adequate remedy at law.

RESPONSE: Paragraph 58 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 58.

COUNT II
(INFRINGEMENT OF THE '840 PATENT)

59. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

RESPONSE: Paragraph 59 contains no allegations of fact to which a response is required. To the extent a response is required, Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

60. Upon information and belief, Sandoz filed ANDA No. 213570 seeking approval to manufacture, use, import, offer to sell and/or sell Sandoz's generic products in the United States before the expiration of the '840 patent.

RESPONSE: Sandoz admits that it is seeking FDA approval to commercially manufacture, use, or sell Sandoz's ANDA Products in the United States. Sandoz denies the remaining allegations of Paragraph 60.

61. Upon information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '840 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Sandoz admits the allegations of Paragraph 61.

62. Upon information and belief, in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

RESPONSE: Sandoz admits that in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's ANDA Products are bioequivalent to the corresponding strengths of REXULTI® Tablets. Sandoz denies the remaining allegations of Paragraph 62.

63. Sandoz has actual knowledge of Otsuka's '840 patent, as evidenced by Sandoz's Notice Letter.

RESPONSE: Sandoz admits that it was aware of the '840 patent at least as early as September 18, 2019. Sandoz denies the remaining allegations of Paragraph 63.

64. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed one or more claims of the '840 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213570, seeking approval to commercially manufacture, use, import, offer to sell or sell Sandoz's generic products before the expiration date of the '840 patent.

RESPONSE: Paragraph 64 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 64.

65. Upon information and belief, if ANDA No. 213570 is approved, Sandoz will infringe one or more claims of the '840 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Sandoz's generic Case

approval of ANDA No. 213570 shall be no earlier than the expiration of the '840 patent and any additional periods of exclusivity.

RESPONSE: Paragraph 65 contains a legal conclusion to which no response is required.

To the extent a response is required, Sandoz denies the allegations of Paragraph 65.

66. Upon information and belief, Sandoz knows, should know and intends that physicians will prescribe and patients will take Sandoz's generic products for which approval is sought in ANDA No. 213570, and therefore will infringe at least one claim of the '840 patent.

RESPONSE: Paragraph 66 contains a legal conclusion to which no response is required.

To the extent a response is required, Sandoz denies the allegations of Paragraph 66.

67. Upon information and belief, Sandoz has knowledge of the '840 patent and, by its proposed package insert for Sandoz's generic products, knows or should know that it will induce direct infringement of at least one claim of the '840 patent, either literally or under the doctrine of equivalents.

RESPONSE: Paragraph 67 contains a legal conclusion to which no response is required.

To the extent a response is required, Sandoz denies the allegations of Paragraph 67.

68. Upon information and belief, Sandoz is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Sandoz's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '840 patent.

RESPONSE: Paragraph 68 contains a legal conclusion to which no response is required.

To the extent a response is required, Sandoz denies the allegations of Paragraph 68.

69. Upon information and belief, if ANDA No. 213570 is approved, Sandoz intends to and will offer to sell, sell and/or import in the United States Sandoz's generic products.

RESPONSE: Sandoz denies the allegations of Paragraph 69.

70. Upon information and belief, Sandoz's actions relating to Sandoz's ANDA No. 213570 complained of herein were done by and for the benefit of Sandoz.

RESPONSE: Sandoz admits that Sandoz Inc. prepared and submitted ANDA No. 213570 to the FDA. Sandoz denies the remaining allegations of Paragraph 70.

71. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless this Court enjoins those activities.

RESPONSE: Paragraph 71 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 71.

72. Plaintiffs do not have an adequate remedy at law.

RESPONSE: Paragraph 72 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 72.

COUNT III
(INFRINGEMENT OF THE '109 PATENT)

73. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

RESPONSE: Paragraph 73 contains no allegations of fact to which a response is required. To the extent a response is required, Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

74. Upon information and belief, Sandoz filed ANDA No. 213570 seeking approval to manufacture, use, import, offer to sell and/or sell Sandoz's generic products in the United States before the expiration of the '109 patent.

RESPONSE: Sandoz admits that it is seeking FDA approval to commercially manufacture, use, or sell Sandoz's ANDA Products in the United States. Sandoz denies the remaining allegations in Paragraph 74 of the Complaint.

75. Upon information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '109 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Sandoz admits the allegations of Paragraph 75.

76. Upon information and belief, in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

RESPONSE: Sandoz admits that in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's ANDA Products are bioequivalent to the corresponding strengths of REXULTI® Tablets. Sandoz denies the remaining allegations of Paragraph 76.

77. Sandoz has actual knowledge of Otsuka's '109 patent, as evidenced by Sandoz's Notice Letter.

RESPONSE: Sandoz admits that it was aware of the '109 patent at least as early as September 18, 2019. Sandoz denies the remaining allegations of Paragraph 77.

78. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed one or more claims of the '109 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213570, seeking approval to commercially manufacture, use, import, offer to sell or sell Sandoz's generic products before the expiration date of the '109 patent.

RESPONSE: Paragraph 78 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 78.

79. Upon information and belief, if ANDA No. 213570 is approved, Sandoz will infringe one or more claims of the '109 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Sandoz's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213570 shall be no earlier than the expiration of the '109 patent and any additional periods of exclusivity.

RESPONSE: Paragraph 79 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 79.

80. Upon information and belief, Sandoz knows, should know and intends that physicians will prescribe and patients will take Sandoz's generic products for which approval is sought in ANDA No. 213570, and therefore will infringe at least one claim of the '109 patent.

RESPONSE: Sandoz denies the allegations of Paragraph 80.

81. Upon information and belief, Sandoz has knowledge of the '109 patent and, by its proposed package insert for Sandoz's generic products, knows or should know that it will induce direct infringement of at least one claim of the '109 patent, either literally or under the doctrine of equivalents.

RESPONSE: Paragraph 81 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 81.

82. Upon information and belief, Sandoz is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Sandoz's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '109 patent.

RESPONSE: Paragraph 82 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 82.

83. Upon information and belief, if ANDA No. 213570 is approved, Sandoz intends to and will offer to sell, sell and/or import in the United States Sandoz's generic products.

RESPONSE: Sandoz denies the allegations of Paragraph 83.

84. Upon information and belief, Sandoz's actions relating to Sandoz's ANDA No. 213570 complained of herein were done by and for the benefit of Sandoz.

RESPONSE: Sandoz admits that Sandoz Inc. prepared and submitted ANDA No. 213570 to the FDA. Sandoz denies the remaining allegations of Paragraph 84.

85. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless this Court enjoins those activities.

RESPONSE: Paragraph 85 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 85.

86. Plaintiffs do not have an adequate remedy at law.

RESPONSE: Paragraph 86 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 86.

COUNT IV
(INFRINGEMENT OF THE '637 PATENT)

87. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

RESPONSE: Paragraph 87 contains no allegations of fact to which a response is required. To the extent a response is required, Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

88. Upon information and belief, Sandoz filed ANDA No. 213570 seeking approval to manufacture, use, import, offer to sell and/or sell Sandoz's generic products in the United States before the expiration of the '637 patent.

RESPONSE: Sandoz admits that it is seeking FDA approval to commercially manufacture, use, or sell Sandoz's ANDA Products in the United States. Sandoz denies the remaining allegations in Paragraph 88 of the Complaint.

89. Upon information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '637 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Sandoz admits the allegations of Paragraph 89.

90. Upon information and belief, in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

RESPONSE: Sandoz admits that in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's ANDA Products are bioequivalent to the corresponding strengths of REXULTI® Tablets. Sandoz denies the remaining allegations of Paragraph 90.

91. Sandoz has actual knowledge of Otsuka's '637 patent, as evidenced by Sandoz's Notice Letter.

RESPONSE: Sandoz admits that it was aware of the '637 patent at least as early as September 18, 2019. Sandoz denies the remaining allegations of Paragraph 91.

92. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed one or more claims of the '637 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213570, seeking approval to commercially manufacture, use, import, offer to sell or sell Sandoz's generic products before the expiration date of the '637 patent.

RESPONSE: Paragraph 92 contains a legal conclusion to which no response is required.

To the extent a response is required, Sandoz denies the allegations of Paragraph 92.

93. Upon information and belief, if ANDA No. 213570 is approved, Sandoz will infringe one or more claims of the '637 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Sandoz's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213570 shall be no earlier than the expiration of the '637 patent and any additional periods of exclusivity.

RESPONSE: Paragraph 93 contains a legal conclusion to which no response is required.

To the extent a response is required, Sandoz denies the allegations of Paragraph 93.

94. Upon information and belief, Sandoz knows, should know and intends that physicians will prescribe and patients will take Sandoz's generic products for which approval is sought in ANDA No. 213570, and therefore will infringe at least one claim of the '637 patent.

RESPONSE: Paragraph 94 contains a legal conclusion to which no response is required.

To the extent a response is required, Sandoz denies the allegations of Paragraph 94.

95. Upon information and belief, Sandoz has knowledge of the '637 patent and, by its proposed package insert for Sandoz's generic products, knows or should know that it will induce direct infringement of at least one claim of the '637 patent, either literally or under the doctrine of equivalents.

RESPONSE: Paragraph 95 contains a legal conclusion to which no response is required.

To the extent a response is required, Sandoz denies the allegations of Paragraph 95.

96. Upon information and belief, Sandoz is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Sandoz's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '637 patent.

RESPONSE: Paragraph 96 contains a legal conclusion to which no response is required.

To the extent a response is required, Sandoz denies the allegations of Paragraph 96.

97. Upon information and belief, if ANDA No. 213570 is approved, Sandoz intends to and will offer to sell, sell and/or import in the United States Sandoz's generic products.

RESPONSE: Sandoz denies the allegations of Paragraph 97.

98. Upon information and belief, Sandoz's actions relating to Sandoz's ANDA No. 213570 complained of herein were done by and for the benefit of Sandoz.

RESPONSE: Sandoz admits that Sandoz Inc. prepared and submitted ANDA No. 213570 to the FDA. Sandoz denies the remaining allegations of Paragraph 98.

99. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless this Court enjoins those activities.

RESPONSE: Paragraph 99 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 99.

100. Plaintiffs do not have an adequate remedy at law.

RESPONSE: Paragraph 100 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 100.

COUNT V
(INFRINGEMENT OF THE '419 PATENT)

101. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

RESPONSE: Paragraph 101 contains no allegations of fact to which a response is required. To the extent a response is required, Sandoz repeats and incorporates by reference its responses to each of the preceding paragraphs as if fully set forth herein.

102. Upon information and belief, Sandoz filed ANDA No. 213570 seeking approval to manufacture, use, import, offer to sell and/or sell Sandoz's generic products in the United States before the expiration of the '419 patent.

RESPONSE: Sandoz admits that it is seeking FDA approval to commercially manufacture, use, or sell Sandoz's ANDA Products in the United States. Sandoz denies the remaining allegations in Paragraph 102 of the Complaint.

103. Upon information and belief, Sandoz filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '419 patent are invalid, unenforceable and/or not infringed.

RESPONSE: Sandoz admits the allegations of Paragraph 103.

104. Upon information and belief, in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

RESPONSE: Sandoz admits that in its ANDA No. 213570, Sandoz has represented to the FDA that Sandoz's ANDA Products are bioequivalent to the corresponding strengths of REXULTI® Tablets. Sandoz denies the remaining allegations of Paragraph 104.

105. Sandoz has actual knowledge of Otsuka's '419 patent, as evidenced by Sandoz's Notice Letter.

RESPONSE: Sandoz admits that it was aware of the '419 patent at least as early as September 18, 2019. Sandoz denies the remaining allegations of Paragraph 105.

106. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Sandoz has infringed one or more claims of the '419 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213570, seeking approval to commercially manufacture, use, import, offer to sell or sell Sandoz's generic products before the expiration date of the '419 patent.

RESPONSE: Paragraph 106 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 106.

107. Upon information and belief, if ANDA No. 213570 is approved, Sandoz will infringe one or more claims of the '419 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Sandoz's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213570 shall be no earlier than the expiration of the '419 patent and any additional periods of exclusivity.

RESPONSE: Paragraph 107 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 107.

108. Upon information and belief, Sandoz's actions relating to Sandoz's ANDA No. 213570 complained of herein were done by and for the benefit of Sandoz.

RESPONSE: Sandoz admits that Sandoz Inc. prepared and submitted ANDA No. 213570 to the FDA. Sandoz denies the remaining allegations of Paragraph 108.

109. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless this Court enjoins those activities.

RESPONSE: Paragraph 109 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 109.

110. Plaintiffs do not have an adequate remedy at law.

RESPONSE: Paragraph 110 contains a legal conclusion to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 110.

RESPONSES TO REQUEST FOR RELIEF

Sandoz denies all remaining allegations not specifically admitted herein. Sandoz denies that Plaintiffs are entitled to any judgment or relief against Sandoz and therefore specifically denies paragraphs (A) through (H) of Plaintiff's Request for Relief.

JURY DEMAND

Sandoz demands trial by jury as to all issues so triable.

DEFENSES

Sandoz, without prejudice to the denials set forth in its Answer, alleges the following defenses to Plaintiffs' Complaint. Sandoz reserves the right to seek leave to assert additional defenses based on the Court's claim construction and as it learns more information through discovery. Sandoz does not assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof. Without any admission or implication as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, Sandoz asserts the following defenses:

FIRST DEFENSE
(INVALIDITY OF THE PATENTS IN SUIT)

One or more claims of the patents in suit are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without

limitation, one or more of sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents. For example, without limitation, the patents in suit are invalid for at least the reasons set forth in Sandoz's Notice Letter dated September 18, 2019.

SECOND DEFENSE
(NON-INFRINGEMENT OF THE PATENTS IN SUIT)

The manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Products does not and will not infringe, induce infringement of, or contribute to the infringement of any valid and/or enforceable claims of the patents in suit, either literally or by the doctrine of equivalents. For example, without limitation, the manufacture, use, sale, offer for sale, or importation of the products described in ANDA No. 213570 has not infringed, does not infringe, and would not infringe any valid claim of the patents in suit for at least the reasons set forth in Sandoz's Notice Letter dated September 18, 2019.

THIRD DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

This Court lacks subject matter jurisdiction over any claims asserted under 35 U.S.C. § 271(a), (b), and (c).

FOURTH DEFENSE
(FAILURE TO STATE A CLAIM FOR INDIRECT INFRINGEMENT)

Plaintiffs have failed to state a claim upon which relief can be granted with respect to purported indirect infringement. The Complaint contains only conclusory allegations that "healthcare professionals and/or patients will use Sandoz's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim" of the patents in Suit. As such, Plaintiffs' Complaint fails to state a claim for either induced infringement or contributory infringement.

FIFTH DEFENSE
(NOT AN EXCEPTIONAL CASE)

Sandoz's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

RESERVATION OF DEFENSES

Sandoz hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure, District of Delaware Local Rules, and the U.S. Patent Law as well as any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation, including unenforceability.

COUNTERCLAIMS OF SANDOZ INC.

Sandoz Inc. ("Sandoz"), by and through the undersigned attorneys, brings the following Counterclaims against Plaintiffs/Counterclaim-Defendants Otsuka Pharmaceuticals Co., LTD ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), and alleges as follows:

NATURE OF THE ACTION

1. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. In bringing this action, Sandoz seeks a declaration of non-infringement and/or invalidity of U.S. Patent Nos. 7,888,362 ("'362 patent"), 8,349,840 ("'840 patent"), 8,618,109 ("'109 patent"), 9,839,637 ("'637 patent"), and 10,307,419 ("'419 patent") ("Patents-in-Suit") and a declaration that Sandoz is free to continue to seek approval of its Abbreviated New Drug Application ("ANDA") No. 213570, and upon approval by the U.S. Food and Drug Administration ("FDA") to engage in commercial manufacture, importation, sale, and/or offer for sale of the products described in ANDA No. 213570.

THE PARTIES

2. Defendant/Counterclaim-Plaintiff Sandoz is a corporation organized and existing under the laws of the State of Colorado, with a place of business at 100 College Road West, Princeton, New Jersey 08540.

3. Plaintiff/Counterclaim-Defendant Otsuka purports to be a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

4. Plaintiff/Counterclaim-Defendant Lundbeck purports to be a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Sandoz in this District and because Plaintiffs conduct substantial business in, and have regular contact with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400 and 21 U.S.C. § 355(j)(5)(C)(i)(II).

BACKGROUND

A. Rexulti® (Brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg)

8. Otsuka purports to hold New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) tablets, 0.25, 0.5, 1, 2, 3 and 4 mg.

B. Patents-in-Suit

9. The '362, '840, '109, '637 and '419 patents are listed in the electronic version of the FDA's publication *Approved Drug Products and Therapeutic Equivalence Evaluations* ("Orange Book") in connection with NDA No. 205422.

10. On information and belief, Otsuka and Lundbeck caused the FDA to publish the Patents-in-Suit in the Orange Book in connection with NDA No. 205422 for REXULTI®.

11. Otsuka and Lundbeck purport and claim to have the right to enforce the '362, '840, '109, '637 and '419 Patents.

12. Lundbeck purports to be the exclusive licensee to '362, '840, '109, '637 and '419 patents.

13. On November 1, 2019, the Plaintiffs filed a Complaint in this Court seeking, among other things, a judgment that Sandoz infringed the '362, '840, '109, '637 and '419 patents by submitting ANDA No. 213570; and that making, using, selling, offering to sell, or importing the products described in ANDA No. 213570 ("Sandoz's ANDA Products"), or inducing or contributing to such conduct, would constitute infringement of the '362, '840, '109, '637 and '419 patents. As such, an immediate and justiciable controversy exists between Sandoz, on the one hand, and Plaintiffs, on the other, regarding whether Sandoz's ANDA Products infringe any valid and enforceable claim of the '362, '840, '109, '637 and '419 patents.

C. Sandoz's ANDA No. 213570

14. Sandoz submitted ANDA No. 213570 to FDA, seeking approval to engage in the commercial manufacture, use, or sale of Sandoz's ANDA Products prior to the expiration of the Patents-in-Suit.

15. ANDA No. 213570 includes certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") to the '362, '840, '109, '637 and '419 patents, stating that, in Sandoz's opinion and to the best of its knowledge, such patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Sandoz's ANDA Products.

16. In accordance with the requirements of 21 U.S.C. § 355(b)(3)(B) and 21 C.F.R.§ 314.52(c), Sandoz sent Plaintiffs a Notice Letter dated September 18, 2019 ("Notice Letter"), stating that Sandoz's ANDA No. 213570 included Paragraph IV Certifications, alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz's ANDA Products.

17. Sandoz's Notice Letter included an Offer for Confidential Access ("OCA") to ANDA No. 213570 for the holder of NDA No. 205422 and owner of the Patents-in-Suit so that

each could determine whether Sandoz's ANDA Products infringe any valid and enforceable claim of the Patents-in-Suit, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

18. Pursuant to § 505(j)(2)(B)(iv)(II) of the Federal Food Drug and Cosmetic Act, Sandoz attached to its Notice Letter a detailed statement of the factual and legal bases for Sandoz's Paragraph IV Certifications ("Detailed Statement").

19. Sandoz's Notice Letter initiated a 45-day statutory period during which Plaintiffs had the opportunity to file an action for patent infringement.

20. On November 1, 2019, Plaintiffs sued Sandoz in this District for alleged infringement of the '362, '840, '109, '637 and '419 patents. Sandoz denies all allegations of infringement.

FIRST COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '362 Patent)

21. Sandoz restates, realleges, and incorporates by reference Paragraphs 1-20 as if fully set forth herein.

22. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '362 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and Sandoz concerning the invalidity of the claims of the '362 patent.

23. Because Plaintiffs maintain and Sandoz denies that the '362 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '362 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including

§§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

24. In accordance with 21 U.S.C. § 355(j)(2)(B), through its Notice Letter, which is incorporated herein by reference, Sandoz has provided Plaintiffs with a detailed statement of the factual and legal bases for why the claims of the '362 patent are invalid. Sandoz reserves the right to assert additional grounds of invalidity.

25. Sandoz is entitled to a declaration that the claims of the '362 patent are invalid.

SECOND COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '362 Patent)

26. Sandoz restates, realleges, and incorporates by reference Paragraphs 1-25 as if fully set forth herein.

27. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. There is an actual, substantial, and continuing case or controversy between Sandoz and Plaintiffs regarding, *inter alia*, the noninfringement of the '362 Patent.

28. Sandoz seeks a declaration that no valid or enforceable claim of the '362 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA No. 213570.

29. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '362 patent. Sandoz reserves the right to assert additional grounds of non-infringement.

30. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 213570 would directly and/or indirectly infringe the '362 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA No. 213570 within the United States have not infringed and will not infringe, directly and/or indirectly, the '362 patent.

31. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA No. 213570 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '362 patent.

THIRD COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '840 Patent)

32. Sandoz restates, realleges, and incorporates by reference Paragraphs 1-31 as if fully set forth herein.

33. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '840 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and Sandoz concerning the invalidity of the claims of the '840 patent.

34. Because Plaintiffs maintain and Sandoz denies that the '840 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '840 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including

§§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

35. In accordance with 21 U.S.C. § 355(j)(2)(B), through its Notice Letter, which is incorporated herein by reference, Sandoz has provided a detailed statement of the factual and legal bases for why the claims of the '840 patent are invalid. Sandoz reserves the right to assert additional grounds of invalidity.

36. Sandoz is entitled to a declaration that the claims of the '840 patent are invalid.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '840 Patent)

37. Sandoz restates, realleges, and incorporates by reference Paragraphs 1-36 as if fully set herein.

38. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. There is an actual, substantial, and continuing case or controversy between Sandoz and Plaintiffs regarding, *inter alia*, the noninfringement of the '840 Patent.

39. Sandoz seeks a declaration that no valid or enforceable claim of the '840 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA No. 213570.

40. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '840 patent. Sandoz reserves the right to assert additional grounds of non-infringement.

41. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 213570 would directly and/or indirectly infringe the '840 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA No. 213570 within the United States have not infringed and will not infringe, directly and/or indirectly, the '840 patent.

42. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA No. 213570 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '840 patent.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '109 Patent)

43. Sandoz restates, realleges, and incorporates by reference Paragraphs 1-42 as if fully set herein.

44. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '109 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and Sandoz concerning the invalidity of the claims of the '109 patent.

45. Because Plaintiffs maintain and Sandoz denies that the '109 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '109 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including

§§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

46. In accordance with 21 U.S.C. § 355(j)(2)(B), through its Notice Letter, which is incorporated herein by reference, Sandoz has provided a detailed statement of the factual and legal bases for why the claims of the '109 patent are invalid. Sandoz reserves the right to assert additional grounds of invalidity.

47. Sandoz is entitled to a declaration that the claims of the '109 patent are invalid.

SIXTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '109 Patent)

48. Sandoz restates, realleges, and incorporates by reference Paragraphs 1-47 as if fully set herein.

49. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. There is an actual, substantial, and continuing case or controversy between Sandoz and Plaintiffs regarding, *inter alia*, the noninfringement of the '109 Patent.

50. Sandoz seeks a declaration that no valid or enforceable claim of the '109 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA No. 213570.

51. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '109 patent. Sandoz reserves the right to assert additional grounds of non-infringement.

52. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 213570 would directly and/or indirectly infringe the '109 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA No. 213570 within the United States have not infringed and will not infringe, directly and/or indirectly, the '109 patent.

53. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA No. 213570 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '109 patent.

SEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '637 Patent)

54. Sandoz restates, realleges, and incorporates by reference Paragraphs 1-53 as if fully set herein.

55. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '637 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and Sandoz concerning the invalidity of the claims of the '637 patent.

56. Because Plaintiffs maintain and Sandoz denies that the '637 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '637 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including

§§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

57. In accordance with 21 U.S.C. § 355(j)(2)(B), through its Notice Letter, which is incorporated herein by reference, Sandoz has provided a detailed statement of the factual and legal bases for why the claims of the '637 patent are invalid. Sandoz reserves the right to assert additional grounds of invalidity.

58. Sandoz is entitled to a declaration that the claims of the '637 patent are invalid.

EIGHTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '637 Patent)

59. Sandoz restates realleges, and incorporates by reference Paragraphs 1-58 as if fully set herein.

60. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. There is an actual, substantial, and continuing case or controversy between Sandoz and Plaintiffs regarding, *inter alia*, the noninfringement of the '637 Patent.

61. Sandoz seeks a declaration that no valid or enforceable claim of the '637 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA No. 213570.

62. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '637 patent. Sandoz reserves the right to assert additional grounds of non-infringement.

63. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 213570 would directly and/or indirectly infringe the '637 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA No. 213570 within the United States have not infringed and will not infringe, directly and/or indirectly, the '637 patent.

64. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA No. 213570 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '637 patent.

NINTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '419 Patent)

65. Sandoz restates, realleges, and incorporates by reference Paragraphs 1-64 as if fully set herein.

66. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '419 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and Sandoz concerning the invalidity of the claims of the '419 patent.

67. Because Plaintiffs maintain and Sandoz denies that the '419 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '419 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including

§§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

68. In accordance with 21 U.S.C. § 355(j)(2)(B), through its Notice Letter, which is incorporated herein by reference, Sandoz has provided a detailed statement of the factual and legal bases for why the claims of the '419 patent are invalid. Sandoz reserves the right to assert additional grounds of invalidity.

69. Sandoz is entitled to a declaration that the claims of the '419 patent are invalid.

TENTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '419 Patent)

70. Sandoz restates, realleges, and incorporates by reference Paragraphs 1-69 as if fully set herein.

71. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. There is an actual, substantial, and continuing case or controversy between Sandoz and Plaintiffs regarding, *inter alia*, the noninfringement of the '419 Patent.

72. Sandoz seeks a declaration that no valid or enforceable claim of the '419 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA No. 213570.

73. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '419 patent. Sandoz reserves the right to assert additional grounds of non-infringement.

74. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 213570 would directly and/or indirectly infringe the '419 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA No. 213570 within the United States have not infringed and will not infringe, directly and/or indirectly, the '419 patent.

75. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA No. 213570 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '419 patent.

PRAYER FOR RELIEF

WHEREFORE, Sandoz respectfully requests this Court enter a Judgement and Order:

A. Dismissing the Complaint, and the claims for relief contained therein, with prejudice and denying each and every request for relief contained therein;

B. Declaring that the claims of the '362, '840, '109, '637 and '419 Patents are invalid;

C. Declaring that the manufacture, use, offer for sale, importation, and/or marketing of Sandoz's ANDA Products has not infringed, does not infringe, and would not – if made, used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and enforceable claim of the '362, '840, '109, '637 or '419 patents, either literally or under the doctrine of equivalents;

D. Enjoining Plaintiffs, their officers, employees, agents, representatives, attorneys, and others acting on its behalf, from threatening or initiating infringement litigation against Sandoz or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Sandoz, or charging it either orally or in writing with infringement of the Patents-in-Suit;

E. Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Sandoz its attorney fees, costs, and expenses under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon; and

F. Granting Sandoz such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Sandoz hereby demands a trial by jury of all issues so triable.

Dated: March 16, 2020

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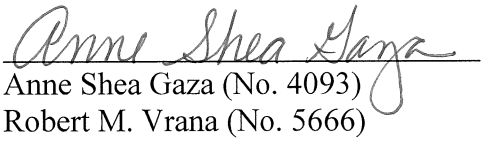

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CERTIFICATE OF SERVICE

I, Anne Shea Gaza, Esquire, hereby certify that on March 16, 2020, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to all registered participants.

I further certify that on March 16, 2020**,** I caused the foregoing document to be served by e-mail on the following counsel of record:

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